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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/811,762	03/19/2001	Virginia Goss Tusher	M-10523 US	8102

36257 7590 10/13/2005
PARSONS HSUE & DE RUNTZ LLP
595 MARKET STREET
SUITE 1900
SAN FRANCISCO, CA 94105

EXAMINER

CLOW, LORI A

ART UNIT PAPER NUMBER

1631

DATE MAILED: 10/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Interview Summary	Application No.	Applicant(s)	
	09/811,762	TUSHER ET AL.	
	Examiner	Art Unit	
	Lori A. Clow, Ph.D.	1631	

All participants (applicant, applicant's representative, PTO personnel):

- (1) Lori A. Clow, Ph.D. (PTO). (3) James Hsue (Apps Rep).
 (2) Marjorie Moran, Primary (PTO). (4) _____.

Date of Interview: 04 October 2005.

Type: a) ☒ Telephonic b) ☐ Video Conference
 c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.
 If Yes, brief description: _____.

Claim(s) discussed: all.

Identification of prior art discussed: Sherer.

Agreement with respect to the claims f) ☐ was reached. g) ☐ was not reached. h) ☒ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See Continuation Sheet.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

MARJORIE A. MORAN
PRIMARY EXAMINER

Marjorie A. Moran
 10/5/05

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Lori A. Clow
 Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: The following points were discussed: 1) Applicant stated that "gene expression values" were inherent in the claims. The Examiners pointed out that this limitation was not inherent and that the proposed claim amendment, removing such a limitation, would potentially lead to an enablement rejection. 2) The Examiners pointed out that there were still limitations in the proposed amendments that include "proteins". It was agreed that if all limitations with regard to "proteins" were removed, the outstanding New Matter rejection would be withdrawn. 3) The Examiners explained to Applicant the basis for the Non-Statutory rejection under 35 USC 101. For example, one proposed way to overcome the outstanding rejection would be for the claims to recite some kind of output, as supported by the originally filed disclosure. 4) The Examiners explained to Applicant the basis for the outstanding Utility rejection under 35 USC 101. Applicant was reminded that an active, positive step of "identifying" in association with the limitation of gene expression, may overcome the outstanding rejection. However, as the claim is instantly recited, there is no actual "identification" such that the claimed method has utility. 5) Finally, Applicant will provide arguments with regard to the outstanding rejection under 35 USC 102. The Examiners admit that the recited prior art reference of Sherer does not appear to teach that which is recited in the instant specification. However, the instant claims (1-7, in particular) are very broad and do encompass the limitations taught by Sherer .

595 Market Street, Suite 1900 San Francisco, CA 94105
tel 415.318.1160 fax 415.693.0194

Date September 30, 2005
To Examiner Lori A. Clow, Ph.D.
United States Patent and Trademark Office
Fax number (571) 273-0715
Tel number (571) 272-0715

From James S. Hsue, Esq.
Total pages 12 (including this cover page)
Subject Examiner Interview via telephone on 10/4/2005
Your Ref. Appln. No. 09/811,762
Our Ref. STAN.058US1

Dear Examiner Clow:

Attached is an Applicant Initiated Interview Request Form, a continuation page 2 of same, and 9 pages of claims.

THIS FACSIMILE IS SENT BY A LAW FIRM AND MAY CONTAIN INFORMATION THAT IS CONFIDENTIAL OR PRIVILEGED If you are not the intended recipient, please notify us immediately and return this facsimile and any attachments to us by mail.

Applicant Initiated Interview Request Form

Application No.: 09/811,762 First Named Applicant: Virginia Goss TUSHER et al.
 Examiner: Lori A. CLOW Art Unit: 1631 Status of Application: pending/non-final

Tentative Participants:

(1) James S. Hsue, attorney (2) Examiner Lori A. Clow
 (3) SPE Marjorie A. Moran (4) _____

Proposed Date of Interview: Tuesday, 10-4-2005 Proposed Time: 1PM (AM/PM)

Type of Interview Requested:

(1) ☒ Telephonic (2) ☐ Personal (3) ☐ Video Conference

Exhibit To Be Shown or Demonstrated: ☐ YES ☐ NO

If yes, provide brief description: _____

Issues To Be Discussed

Issues (Rej., Obj., etc)	Claims/ Fig. #s	Prior Art	Discussed	Agreed	Not Agreed
(1) <u>see pg. 2</u>	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(2) _____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(3) _____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(4) _____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

☒ Continuation Sheet Attached

Brief Description of Arguments to be Presented:

An interview was conducted on the above-identified application on _____.

NOTE: This form should be completed by applicant and submitted to the examiner in advance of the interview (see MPEP § 713.01).

This application will not be delayed from issue because of applicant's failure to submit a written record of this interview. Therefore, applicant is advised to file a statement of the substance of this interview (37 CFR 1.133(b)) as soon as possible.

 Applicant/Applicant's Representative Signature

James S. Hsue

Typed/Printed Name of Applicant or Representative

29,545

Registration Number, if applicable

 Examiner/SPE Signature

This collection of information is required by 37 CFR 1.133. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 21 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Atty Docket: STAN.058US1

CONTINUATION SHEET TO PTOL-413A
APPLICANT INITIATED INTERVIEW REQUEST FORM

Re: Appln. No. 09/811,762

Applicant: Virginia Goss TUSHER et al.

Art Unit: 1631

Issues	Claims	Prior Art
Sec. 112 (New Matter)	1-22, 28-30, 33, 44, 46, 58 and 60	
Sec. 101 Non-statutory Subject matter	same as above	
Sec. 101/112 Utility	same as above	
Sec. 102(a) and 102(e)	1-7, 16, 17, 28, 44, 58 and 60	Scherer

Brief Description of Arguments to be Presented:

Sec. 112 new matter Please see amended claims attached.

Sec. 101/112:

Non-statutory Subject matter: Similar to the method claims in the Arrhythmia case, the rejected claims manipulate data corresponding to physical objects or activities external to the computer. See MPEP 2106 Part IV, subpart B 2(b)I on pages 2100-14 to 2100-17.

Utility: Please see paper entitled "Significance Analysis of microarrays applied to the ionizing radiation response" published by the inventors on line at www.pnas.org/cgi/content/full/98/5116. Paper has been cited by over 1,000 other articles. Method of rejected claims practiced by papers citing article by the inventors. See for example, "An expression signature for p53 status in human breast cancer predicts mutation status, transcriptional effects, and patient survival," at www.pnas.org/cgi/content/full/102/38/13550. See p. 6 of the article and reference to reference 22.

Sec. 102(a) and 102(e) Scherer fails to teach or suggest at least the adjusting, deriving and comparing of claim 1, and aspects of other rejected claims.